APR 15 2005

510(k) Summary of Safety and Effectiveness for the MAX Engineering Ltd. Spectra-SP Laser System K050254

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	MAX Engineering Ltd. 421 Ilsan Technotown 1141-1 Baeksuk, Ilsan Goyang, Gyunggi, Republic of Korea 411-360
Contact Person:	Maureen O'Connell 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	January 26, 2005

2. Names

Device Name:	Spectra-SP Laser System
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. Predicate Devices

The Spectra-SP Laser System is substantially equivalent to a combination of the Lumenis Family of UltraPulse SurgiTouch CO2 Laser Systems (K030147), the Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers and Delivery Device Accessories (K022060), the Lumenis Compact 20C, 30C and 40C CO2 Lasers (K935563 and K963229), the ESC Medical Systems Luxar LX-20 CO2 Surgical Laser System Family (K991628 and K960475), and the MedArt Uni-Laser 450P CO2 Laser System & Accessories (K991297).

4. Device Description

The Spectra-SP Laser System consists of a self-contained console, an articulated arm delivery system, a footswitch and a pair of goggles. The Spectra-SP Laser

produces a beam of coherent infrared (10.6μm) and has dual operation mode. (Continuous Wave & Char-Free)

The main console is the heart of the Spectra-SP Laser and contains the optical system (with DC-Excited Sealed-off Carbon Dioxide GAS Tube), cooling system, arm mount, micro-controller, and power supply. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the control panel. There are 4 casters in the console base for moving.

The laser beam exits an articulated arm into a handpiece where it is focused by the final focus lens contained in the handpiece to produce a spot size at the treatment focal plane. The handpiece components, when inserted in the beam delivery system, change the laser beam characteristics.

5. **Indications for Use**

The Spectra-SP Laser System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

-Laser skin resurfacing

-Treatment of wrinkles, rhytids and furrows

-Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas) tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology, Plastic Surgery & General Surgery

Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Soft Tissue Dental

The specific soft tissue dental indications include: Periodontic procedures such as gingivectomy-removal of hyperplasias, gingivoplasty, and incision and excision;

Oral surgery such as frenectomy, incisional and excisional biopsy, incision and excision of aphous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, homeostatis, operculectomy, and crown lengthening.

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

Gynecology
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

6. **Performance Data**
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

MAX Engineering Ltd.
C/o Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K050254
Trade/Device Name: Spectra-SP Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 22, 2005
Received: March 23, 2005

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name Spectra-SP Laser System K050254

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over The Counter Use _____

(Optional Format 1-2-96)

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